

# APO-go<sup>®</sup> Ampoules 10mg/ml

Solution for Injection\*  
Apomorphine hydrochloride

## PACKAGE LEAFLET: Information for the User

\* Abbreviated to APO-go Ampoules in the text

### Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, nurse or pharmacist.
- This medicine has been prescribed for you. Do not give it to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, nurse or pharmacist.

### In this leaflet:

1. What APO-go Ampoules is and what it is used for
2. Before you use APO-go Ampoules
3. How to use APO-go Ampoules
4. Possible side effects
5. How to store APO-go Ampoules
6. Further information

## 1. What APO-go Ampoules is and what it is used for

APO-go Ampoules contains apomorphine solution for injection. It is injected into the area under the skin (subcutaneously). The active ingredient in APO-go Ampoules is apomorphine hydrochloride. There is 10 mg of apomorphine in each millilitre of solution.

Apomorphine hydrochloride belongs to a group of medicines known as dopamine agonists. APO-go Ampoules is used to treat Parkinson's disease. Apomorphine helps reduce the amount of time spent in an 'off' or immobile state in people who have previously been treated for Parkinson's disease with levodopa (another treatment for Parkinson's disease) and/or other dopamine agonists. Your doctor or nurse will help you to recognise the signs of when to use your medicine.

Despite the name, apomorphine does not contain morphine.

## 2. Before you use APO-go Ampoules

### Do not use APO-go Ampoules

- if you are under 18 years of age
- if you have breathing difficulties
- if you have dementia or Alzheimer's disease
- if you suffer from a mental illness with symptoms such as hallucinations, delusions, disordered thoughts, loss of contact with reality
- if you have liver problems
- if you have severe dyskinesia (involuntary movements) or severe dystonia (inability to move) despite taking levodopa
- if you are allergic to apomorphine or any of the other ingredients of APO-go Ampoules (for other ingredients, see section 6)
- if you or someone in your family are known to have an abnormality of electrocardiogram (ECG) called "long QT syndrome". Tell your doctor.

### Take special care with APO-go Ampoules:

Please inform your doctor, nurse or pharmacist:

- if you have kidney problems
- if you have lung problems
- if you have heart problems
- if you have low blood pressure or feel faint and dizzy when you stand
- if you are taking any medicines to treat high blood pressure
- if you feel sick or suffer from being sick
- if your Parkinson's disease causes certain mental problems such as hallucinations and confusion
- if you are elderly or frail.

### Check with your doctor or pharmacist before taking your medicine if:

you are using medicines that are known to affect the way your heart beats. This includes medicines used for heart rhythm problems (such as quinidine and amiodarone), for depression (including tricyclic antidepressants such as amitriptyline and imipramine) and for bacterial infections ('macrolide' antibiotics such as erythromycin, azithromycin and clarithromycin) and domperidone.

### Taking other medicines

If you use APO-go Ampoules with other medicines the effect of those medicines may be altered. This is especially true for:

- Medicines such as clozapine to treat some mental disorders
- Medicines to lower your blood pressure
- Other medicines for Parkinson's disease

Your doctor will tell you if you need to change the dose of your apomorphine or any of your other medicines.

If you are taking levodopa (another medicine for Parkinson's disease) as well as apomorphine your doctor should check your blood regularly.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

### Using APO-go Ampoules with food and drink

Food and drink do not affect the way APO-go Ampoules will work.

### Pregnancy and breast-feeding

APO-go Ampoules should not be used during pregnancy unless clearly necessary. Check with your doctor or nurse before using APO-go Ampoules if you are pregnant, think you may be pregnant or you are planning to become pregnant.

It is not known whether APO-go Ampoules is transferred to breast milk. Talk to your doctor if you are breast-feeding or intend to breast-feed. Your doctor will explain to you, whether you should continue/discontinue breast-feeding or continue/discontinue taking this medicine.

Ask your doctor or pharmacist for advice before using any medicine.

### Driving and using machines

APO-go Ampoules can cause drowsiness and a strong desire to sleep. Do not drive or use any tools or machinery if APO-go Ampoules affects you in this way.

### Information about the ingredients of APO-go Ampoules

APO-go Ampoules contains sodium metabisulphite which rarely can cause a severe allergic reaction with symptoms such as rash or itchy skin, difficulty breathing, puffiness of the eyelids, face or lips, swelling or redness of the tongue. If you experience these side effects, immediately go to the nearest hospital casualty department.

APO-go Ampoules contain less than 1 mmol (23mg) of sodium per 10ml, i.e. essentially sodium free.

## 3. How to use APO-go Ampoules

Always use APO-go Ampoules exactly as your doctor has told you. You should check with your doctor, nurse or pharmacist if you are not sure.

Domperidone should be taken at least 2 days before APO-go Ampoules is started to stop you feeling or being sick.

### Do not use APO-go Ampoules if

- The solution has turned green
- The solution is cloudy or you can see particles in it.

### Where to inject your APO-go Ampoules

- Inject your APO-go Ampoules into an area under the skin (subcutaneously) as shown by your doctor or nurse.
- Do not inject APO-go Ampoules into a vein.

### How much to use

The amount of APO-go Ampoules you should use and the number of injections required each day will depend upon your personal needs. Your doctor will discuss this with you and tell you how much of your medicine you should inject and how often. The amount that will work best for you will have been determined during your visit to the specialist clinic.

- The usual daily dose is between 3 mg and 30 mg
- You may need as much as 100 mg per day
- Typically, you will need between 1 and 10 injections each day
- Each injection should not be more than 10 mg.

If your symptoms are not controlled well enough with separate injections or if you find you are requiring more than 10 injections per day, you may require a continuous infusion of apomorphine. Your doctor or nurse will decide if you need this. For a continuous infusion:

- The usual dose is between 1 mg and 4 mg per hour
- Usually this is given to you when you are awake and stopped before you go to sleep
- A different site for each infusion should be used every 12 hours.

The choice of which minipump and/or syringe driver to use will be decided by your doctor. You should check with your doctor, nurse or pharmacist if you are not sure.

### What you need to inject APO-go Ampoules

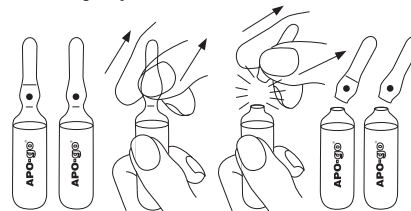
For an injection, you will need:

- One syringe and needle
- A bin called a "Sharps" bin to dispose safely of the used needles and glass containers. These are available from your doctor or pharmacist. Alternatively, use another suitable container such as an empty coffee jar.

### How to open APO-go Ampoules

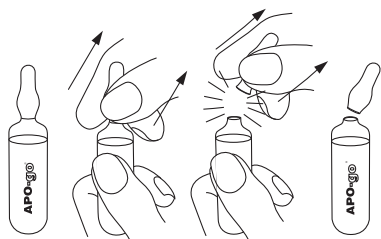
There are 2 different types of ampoule

#### 1) Ampoules with a single spot:



- Locate the **spot** positioned directly above the short score mark on the thin part of the neck. This score is the breaking point of the ampoule.
- Hold the bottom of the ampoule in one hand
- **Cover the spot with your thumb** and use your forefinger to grasp the neck of the ampoule as shown in the diagram.
- Apply pressure with your thumb covering the spot in a **backward** direction.
- Carefully dispose of the top of the ampoule in a "Sharps" bin.

## 2) Ampoules with a complete ring(s):



- Locate the **ring(s)** on the thinnest part of the neck. This score is the breaking point of the ampoule.
- Hold the bottom of the ampoule in one hand.
- Grasp the neck of the ampoule just above the ring as shown in the diagram.
- Apply pressure in a **backward** direction. This will snap off the top of the ampoule.
- Carefully dispose of the top of the ampoule in a “Sharps” bin.

### Once opened APO-go Ampoules should be used immediately

#### Injecting APO-go Ampoules

- Place the needle firmly on the end of the syringe
- Withdraw the volume you require for your dose as advised by your doctor or nurse
- You may need to dilute APO-go Ampoules before use. Your doctor or nurse will have told you if you need to do this and how to do it
- Inject your medicine as shown by your doctor or nurse into an area under the skin (subcutaneously)
- Discard used syringes, needles and ampoules in a “Sharps” bin (available from your doctor or pharmacist) or other suitable container, such as an empty coffee jar
- Take care not to splash any of the solution onto yourself or the carpet as it may stain green.

If you have any further questions about the use of this medicine, ask your doctor or nurse.

#### If you use more APO-go Ampoules than you should

- Tell your doctor or contact your nearest hospital emergency department immediately
- You may experience a slow heart rate, excessive sickness, excessive sleepiness and/or difficulty breathing. You may also feel faint or dizzy particularly when you stand up, due to low blood pressure. Lying down and raising your feet may help you to feel better.

#### If you forget to use APO-go Ampoules

Take it when you next require it. Do not take a double dose to make up for a forgotten dose.

#### If you stop using APO-go Ampoules

Do not stop using APO-go Ampoules without first talking with your doctor.

If you have any further questions on the use of this medicine, ask your doctor, nurse or pharmacist.

## 4. Possible side effects

Like all medicines, APO-go Ampoules can cause side effects, although not everybody gets them.

If you experience an allergic reaction **stop** taking APO-go Ampoules and contact a doctor or your nearest hospital emergency department **immediately**.

The signs of an allergic reaction may include:

- Rash
- Breathing difficulties
- Swelling of the face, lips, throat or tongue

APO-go Ampoules may sometimes cause the following:

#### Very common side effects (affect more than 1 in 10 people):

- Lumps under the skin at the site of injection which are sore, troublesome and may be red and itchy. In order to avoid getting these lumps, it is advisable to change the site of injection every time you insert the needle.

#### Common side effects (affect less than 1 in 10 people):

- Feeling sick or being sick, particularly when starting APO-go Ampoules. If you are taking domperidone and still feel sick, or if you are not taking domperidone and you feel sick, tell your doctor or nurse as soon as possible
- Feeling tired or extremely sleepy
- Confusion or hallucinations
- Yawning
- Feeling dizzy or light-headed when standing up.

#### Uncommon side effects (affect less than 1 in 100 people):

- Increased involuntary movements or increased shakiness during ‘on’ periods
- Haemolytic anaemia, an abnormal breakdown of red blood cells in the blood vessels or elsewhere in the body. This is an uncommon side effect that can occur in patients also taking levodopa

- Rashes
- Breathing difficulties
- Injection site ulceration
- Reduction in red blood cells which can make the skin pale yellow and cause weakness or breathlessness
- Reduction in blood platelets, which increases the risk of bleeding or bruising.

#### Rare side effects (affect less than 1 in 1000):

- An allergic reaction
- Eosinophilia, an abnormally high amount of white blood cells in the blood or in body tissues.

#### Side effects occurring in an unknown number of users:

- Pathological gambling (failure to resist gambling impulses despite serious personal or family consequences)
- Increased sex drive
- Hypersexuality (altered sexual interest and behaviour of significant concern to the patient or to others)
- Swelling of the legs, feet or fingers.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, nurse or pharmacist.

## 5. How to Store APO-go Ampoules

Keep out of the reach and sight of children.

Do not store above 25°C. Store in original carton to protect from light.

Do not use APO-go Ampoules after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Once you have opened the ampoule, use it immediately.

Do not use if the solution has turned green. It should only be used if the solution is clear and colourless.

Used syringes, needles and ampoules should be discarded in a “Sharps” bin or other suitable container, such as an empty coffee jar. When your “Sharps” bin or container is full, please give it to your doctor or pharmacist for safe disposal.

Medicines should not be disposed of via wastewater or household waste.

Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## 6. Further Information

#### What APO-go Ampoules contains

The active substance is apomorphine hydrochloride. Each millilitre of APO-go Ampoules contains 10 mg of apomorphine hydrochloride.

APO-go Ampoules is available in either 2 ml ampoules containing 20 mg of apomorphine hydrochloride or 5 ml ampoules containing 50 mg of apomorphine hydrochloride.

APO-go Ampoules also contain:

- Sodium metabisulphite (E223)
- Hydrochloric acid (or sodium hydroxide)
- Water for Injections

Refer to ‘Section 2: Information about the ingredients of APO-go Ampoules’ regarding sodium metabisulphite.

#### What APO-go Ampoules looks like

APO-go Ampoules is a solution for injection or infusion. The solution is clear and colourless.

#### Contents of the pack

Each pack of APO-go Ampoules contains 5 ampoules in a cardboard carton.

#### Marketing Authorisation Holder and Manufacturer

Genus Pharmaceuticals

Park View House, 65 London Road, Newbury, Berkshire RG14 1JN, United Kingdom.

#### Manufacturer(s)

Recipharm Limited  
Vale of Bardsley, Ashton-under-Lyne  
Lancashire OL7 9RR, United Kingdom

**OR** Kern Pharma S.L.  
Pol. Ind. Colon II, E-08228  
Terrassa (Barcelona), Spain

**OR** Laboratoire Aguetant  
1 Rue Alexander Fleming, BP 7144  
69353 Lyon, Cedex 07, France

**OR** Britannia Pharmaceuticals Ltd  
41-51 Brighton Road, Redhill  
Surrey RH1 6YS, United Kingdom

#### Distributor in the UK

Genus Pharmaceuticals  
Park View House, 65 London Road  
Newbury, Berkshire RG14 1JN  
United Kingdom

#### Distributor in Ireland

Clonmel Healthcare Ltd  
Waterford Road  
Clonmel  
County Tipperary, Ireland

#### This leaflet was last approved in

02/2010

If this leaflet is difficult to see or read and you would like it in a different format, please contact Genus Pharmaceuticals, Park View House, 65 London Road, Newbury, Berkshire RG14 1JN, United Kingdom.